DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2004

SPO Medical Equipment Limited
C/O Ms. Ahava M. Stein
Consulting
20 Hata'as Street, Suite 213
44425 Kfar Saba
ISRAEL

Re: K040178
Trade/Device Name: PulseOx 7500 WristWatch Device, PulseOx 5500 Finger Device
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 17, 2004
Received: August 23, 2004

Dear Ms. Stein:

This letter corrects our substantially equivalent letter of September 10, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K040178**

Device Name: **PulseOx 5500 Finger Device**

Indications For Use:

The SPO PulseOx 5500 Pulse Oximeter is indicated for use for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in hospitals, medical facilities, home care, transport and sub-acute environment.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040178

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number (if known): **K040178**

Device Name: **PulseOx 7500 WristWatch Device**

Indications For Use:

The SPO PulseOx 7500 Pulse Oximeter, a small, wrist-worn device, is indicated for use in measuring, displaying and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It may be used for spot checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, sub-acute and sleep study environments.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040178

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SEP 1 0 2004

K040178

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

1. Applicant:

SPO Medical Equipment Ltd.
Kfir Barkan Bldg.
3 Hagavish Str.
P.O.B. 2454
Kfar Saba 44425
ISRAEL
Tel: +972-8-6842332
Fax: +972-8-6842374

2. Corresponding Official:

Ahava M. Stein, Consultant
A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as Str., Suite 213
44425 Kfar Saba, ISRAEL
Tel: +972-9-7670002
Fax: +972-9-7668534

3. Device Name and Classification

Pulse Oximeter, CFR classification section 870.2700

4. Device trade or proprietary name:

PulseOx 5500 Finger Device

PulseOx 7500 WristWatch Device

5. Common Name:

Pulse Oximeter

6. Classification Name:

CFR classification section 870.2700 and product code DQA, Class II.

7. Description of the Device

The SPO PulseOx pulse oximeter devices monitor the oxygen saturation levels in the blood by pulse oximetry, i.e., changes in light intensity as the light is reflected back from human tissue. Two or more different wavelengths (in the visible and infrared wavelength) are used. Comparisons between the standard signal and the variances can be used to calculate the oxygen saturation of arterial blood. The SPO PulseOx pulse oximeter devices are based on a technology that utilizes the reflective method whereby the sensor is located on one side of the relevant body part so as to measure the necessary parameters.

The main components of the SPO pulse oximeter devices are a sensor block, analog block, controller, LCD display and battery.

8. Intended Use:

PulseOx 5500

The SPO PulseOx 5500 Pulse Oximeter is indicated for use for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in hospitals, medical facilities, home care, transport and sub-acute environments.

PulseOx 7500

The SPO PulseOx 7500 Pulse Oximeter, a small, wrist-worn device, is indicated for use is measuring, displaying and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It may be used for spot checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, sub-acute and sleep study environments.

9. Performance Data:

The following performance tests have been performed on the SPO pulse oximeter devices:

Bench Studies

Bench studies were performed to verify that the PulseOx devices meet their specifications. Tests results showed that the devices perform within their specification and according to the requirements of FDA Draft Guidance Document of the Non-Invasive Pulse Oximeter.

Software Validation

Software Validation according to the IEC60601-1-4 standard and the FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

Electrical Safety and Electromagnetic Compliance

The device was tested according to the following recognized standards:

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety;

IEC 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Test results showed that the PulseOx device meet the requirements of these standards.

Environmental Testing

The PulseOx device will undergo environmental and mechanical testing in accordance with FDA Reviewer Guidance for Premarket Notification Submissions; November 1993; Anesthesiology and Respiratory Device Branch; Division of Cardiovascular, Respiratory and Neurological Devices.

Clinical Studies

The performance of the PulseOx devices was validated by three clinical studies:

- A comparison of PulseOx, Masimo/Radical and Arterial Blood Sampling.
- A comparison of PulseOx 5500/7500 models to Masimo/Radical.
- Evaluation of precision and accuracy of a reflectance pulse oximeter in comparison to a standard pulse oximeter in adult patients.

In addition, a meta-analysis was performed to compare the performance of the PulseOx devices to blood sampling testing results in accordance with FDA Draft Guidance Document on Non-Invasive Pulse Oximeters. Analysis results show a sufficient correlation to the Gold Standard.

10. Predicate Devices

The PulseOx pulse oximeter devices are substantially equivalent to the combination of the Onyx 9500 Pulse Oximetry device (manufactured by Nonin Medical Inc., and subject of 510(k) document no. K001085), the PulSox-3 (manufactured by Minolta and the subject of 510(k) document no. K984570), the Masimo Radical Pulse Oximeter (manufactured by Masimo Corp. and the subject of 510(k) document no. K992340) and to the 3100 WristOx Wrist Pulse Oximeter (manufactured by Nonin Medical Inc. and subject of 510(k) document no. K030668).

11. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the PulseOx pulse oximeter devices are substantially equivalent to the predicate devices cited above as demonstrated in Section 3 of the 510(k) submission.